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PROVISIONAL APPLICATION

OF

Michael M. Kamrava

FOR

UNITED STATES PATENT

ON

HYBRID INSERTION ARM FOR ENDOSCOPICALLY ASSISTED EMBRYO IMPLANTATION

60261461.011201

Docket No.: WCIMC-045799
Sheets of Drawings: 4

31608.1

Michael M. Kamrava, M.D.
West Coast Infertility Medical Clinic, Inc.
250 North Robertson Boulevard
Beverly Hills, California 90211
Tel.: (310) 285-0333
Fax: (310) 285-0334

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PATENT
WCIMC-045799

HYBRID INSERTION ARM FOR ENDOSCOPICALLY ASSISTED EMBRYO IMPLANTATION

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to the field of embryo implantation into the endometrial lining of the uterus of an in-vitro fertilized (IVF) embryo. More particularly, a hybrid endoscope insertion arm has been developed with a flexible free end extending seamlessly from a rigid base section.

2. Description of the Related Arts

Improving the success of IVF depends on many factors, one of which is the delivery or transfer of the embryo to the endometrial lining of the uterus and the successful implantation of the embryo therein. It is well known in the art that assisting an embryo to adhere to, or implant within, a pre-determined area of the endometrial lining of the uterine wall, as opposed to simply releasing the embryo into the uterus, will enhance the success of IVF, minimize the risk of tubal pregnancies and reduce high-order multiple births.

Accordingly, applicant in his co-filed Utility Patent Application entitled "Method and Apparatus for Assisted Embryo Implantation" has developed a minimally invasive embryo transfer method, which uses a specially formed microcatheter to gently deliver one or more selected embryos into a pocket formed

within the endometrial lining. Useful in that method is the within endoscopic device which is fitted with the hybrid arm detailed herein.

This hybrid arm (FIG. 1B) provides a superior stable and maneuverable platform from which to accomplish the microsurgical tasks associated with embryo implantation into a subject's endometrial lining (FIG. 2A).

SUMMARY OF THE INVENTION

A hysteroscope (FIG. 1) is a specialized endoscopic device, for intrauterine use, which provides for direct or video observation of the interior of a subject's uterus. The hysteroscope of this preferred embodiment also provides for minimally invasive operative access to the interior of the subject's uterus (FIG. 2) via a single operative channel. To enhance the field of vision of the endoscope and to increase the maneuverability of the endoscope within the uterus, often the uterus will be insufflated with a pressurized gas thereby distending the uterine walls. To accomplish the insufflation, a gas feed line will be attached to a gas port on the hysteroscope which feeds into the operative channel.

A hysteroscopic device for performing a minimally invasive microsurgical intrauterine procedure should have the following features:

1. The size should be small enough so that the subject's uterus may be accessed without inducing dilation;
2. The insertion should be comfortable and easy to accomplish; and

3. It should provide a stable, yet maneuverable, support for the microsurgical tools.

The improved hysteroscope with hybrid arm of the present invention has an insertion arm which is kept to a minimum diameter by using the same operative channel for gas insufflation and for microcatheter insertion. The distal tip of the hybrid arm has an edge radius to form a gentle insertion head (**FIG. 1C**), and the hybrid rigid and flexible arm provides a far more stable operative platform for the microsurgery of the endometrial lining and embryo implantation.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a side view of the preferred embodiment of the hysteroscope for intrauterine embryo implantation.

FIG. 1B is a perspective view of the preferred embodiment of the hysteroscope for intrauterine embryo implantation.

FIG. 1C is a side view of the distal tip of the hybrid insertion arm of the preferred embodiment.

FIG. 1D is a front view of the distal tip of **FIG. 1C**.

FIG. 2A is a first representative view of the hysteroscope being used for an embryo implantation procedure.

FIG. 2B is a second representative view of the hysteroscope being used for an embryo implantation procedure.

FIG. 3A is a side view of a prior art microcatheter.

FIG. 3B is a side view of a hybrid microcatheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

Referring now to the drawings, illustrated in **FIGS. 1A-1D** is the preferred embodiment of the hysteroscope generally designated **100**. During many types of embryo transfer procedures, a hysteroscope **10** (which is a specialized endoscopic device) is inserted into the subject's uterus and used for direct visual inspection of the endometrial lining and/or for embryo transfer or implantation (**FIGS. 2A** and **2B**).

The hysteroscope **10** of the preferred embodiment is: Reorder#: "Special - Kamrava", manufactured to applicant's specifications by "5 Star Medical, Inc.," of Hayward, California. This hysteroscope **10** is a two-part elongated tubular device, with an operational section **11** at one end and the improved hybrid insertion arm **12** at the other end. Supported on the operational section **11** is an eye-piece **13**, used to visualize inside the uterus, a control knob **14**, used to maneuver the control structure (not shown) within the hybrid insertion arm **12**, and a series of access ports **15-17** traveling from the control section **11** inside both the rigid **18** and the flexible sections **19** which form the hybrid insertion arm **12**. The access ports **15-17** exit or terminate at the distal end **30** of the hysteroscope **10** through the guide face **31**.

To further improve the hybrid insertion arm **12**, the corner of the distal end **30** has an edge radius **32** to facilitate gradual and gentle insertion through the subject's cervix, which will cause less trauma than a blunt ended instrument and is able to gain entry into a smaller opening than a blunt instrument. To further aid the operator

during insertion, a series of locator marks **33** may be added to the hybrid insertion arm **12** to help the operator gauge the position of the hybrid insertion arm **12**.

The basic structure of endoscopes and hysteroscopes are well known in the art, including the mechanisms for flexing the insertion section, see generally U.S. Patent No. 6,006,002 to *Motoki, et al.* and U.S. Patent No. 4,534,339 to *Collins, et al.* Accordingly, neither a detailed description of the endoscope structure nor the operational structure is provided.

Prior art hysteroscopes with wholly flexible insertion sections are often difficult to control precisely during an intrauterine procedure. In the case of intrauterine microsurgery, the hybrid insertion arm **12**, having a rigid tubular base portion **18**, preferably constructed of a smooth material such as stainless steel, seamlessly grafted to a flexible tubular plastic-like free end **19**, is more easily maneuvered within the uterus (**FIG. 2**) and it provides a more stable platform from which to perform the microsurgery and/or embryo implantation than from a wholly flexible hysteroscopic insertion arm.

The small diameter hybrid insertion arm **12** of the present invention, with both rigid and flexible sections **18** and **19** may be attached to a variety of hysteroscopic devices and should not be limited to being attached to, or supported by, the operational section **11** detailed herein.

To further decrease the diameter of the insertion arm **12**, by allowing for a smaller operative channel **20**, an improved microcatheter (**FIG. 3B**) for use in embryo transfer, implantation and intrauterine microsurgery has been developed by applicant

(FIG. 3B). This improved microcatheter **150** is also useful in-and-of-itself as a miniature microsurgical tool.

A microcatheter is a flexible tube with a base section and a tip section. Shown in **FIG. 3A** is a prior art microcatheter **100**. In the prior art microcatheter **100** the base section **101** and the tip section **102** are formed of the same extruded plastic material. One such prior art microcatheter is embryo transfer catheter manufactured by Cook OB/Gyn of Spencer, IN. However, when the prior art microcatheter **100** is reduced to a diameter of less than 0.833 millimeters, it has been observed to bend and become nonfunctional when it encounters tissue "T".

To overcome the bending problems, some manufacturers have produced "Teflon" based microcatheters which have greater wall strength and are less likely to bend. However, "Teflon" based microcatheters cannot be extruded with a diameter of less than 0.4 millimeters. Therefore, the trade-off for strength has been larger tip diameter.

In the instant invention, applicant has developed a microcatheter **150** with a Teflon base section of about one (1) millimeter in diameter that is resistant to bending **151** and used a clear plastic of polycarbonate material that is not toxic to embryos to form a tip **152** with a diameter of about 400 micrometers. The thin walled clear plastic front section **153** is similar to micropipette and tapers **154** towards the tip **15**. The front section **153** and the base section being of dissimilar materials are bonded **155** together to form the microcatheter **150**. This improved microcatheter **150** both resists bending when it encounters tissue "T" and provides a small diameter tip **152**.

Bonding methods include a sonic weld, solvents, heat, adhesive and other suitable methods.

Often during an intrauterine procedure, uterine insufflation is desirable. Illustrated in the hybrid insertion arm **12** of the present invention is a gas port **15** which feeds into the operational port **16** through the operational guide channel **20** and exits the hysteroscope **10** at the bendable distal end **30**, with a corner angle of deflection between 10 and 30 degrees, through the operational aperture **34** in the guide face **31**, thereby maintaining a minimal diameter of the insertion arm **12** yet providing the insufflation function. Illumination within the subject's uterus "U" may be added via the light aperture **35** which is connected via an illumination fiber optic line **21** to the light port **17**. To provide for direct visualization an eyepiece **13** is connected via fiber optic line **22** to the optical aperture **36**. A lens **37** may be fitted into the distal end **30** at the end of the fiber optic line **21** to enhance visualization.

During an embryo implantation procedure (**FIG. 2**) the operational port **16** receives a microcatheter **50** which is of adequate length to allow its distal end **51** to extend from the guide face **31** through the operational aperture **34**.

The distal end **51** of the microcatheter **50** once positioned within the uterus "U" can be used to perform microsurgery such as the formation of an implantation pocket "P" within the endometrial lining "L" (**FIG. 2B**).

Certain presently preferred embodiments of apparatus and methods for practicing the invention have been described herein in some detail and some potential modifications and additions have been suggested. Other modifications, improvements

and additions not described in this document may also be made without departing from the principles of the invention.

CLAIMS

I Claim:

1. A hybrid insertion arm for a hysteroscope comprising:

a rigid substantially smooth hollow tube, with a base receiving end, a front end and having an interior space adequate to accommodate:

- a control structure;
- at least one operative guide channel;
- a fiberoptic line for viewing;
- an illumination fiberoptic line;

a flexible hollow tube, smoothly attached at its base to said front end of said rigid substantially smooth hollow tube, having a distal end and having an interior space adequate to accommodate:

- a control structure;
- at least one operative guide channel;
- a fiberoptic line;
- an illumination fiberoptic line;

a guide face affixed to said distal end through which said operative guide channel opens and onto which said fiberoptic and illumination lines terminate; and,

a corner radius formed around the periphery of said guide face thereby tapering said distal end, thereby facilitating insertion of the distal end into a smaller opening than can be accomplished with a blunt distal end.

2. The hybrid insertion arm for the hysteroscope of claim 1 further comprising a lens fitted in said distal end between the end of said fiber optic line and said guide face.

3. The hybrid insertion arm for the hysteroscope of claim 1 wherein said rigid substantially smooth hollow tube is formed of stainless steel.

4. The hybrid insertion arm for the hysteroscope of claim 1 wherein the outer diameter of said hybrid insertion arm is greater than 8 millimeters.

5. The hybrid insertion arm for the hysteroscope of claim 1 wherein the outer diameter of said hybrid insertion arm is between 2 and 6 millimeters.

6. The hybrid insertion arm for the hysteroscope of claim 1 wherein the flexibility of the distal end is between a corner angle of deflection of 10 and 30 degrees.

7. A hysteroscope comprising:

a control section connected to an insertion arm at one end;

a hybrid insertion arm further comprising:

a rigid substantially smooth hollow tube, with a base receiving end, a front end and having an interior space adequate to accommodate:

- a control structure;
- at least one operative guide channel;
- a fiberoptic line for viewing;
- an illumination fiberoptic line;

a flexible hollow tube, smoothly attached at its base to said front of said rigid substantially smooth hollow tube end, having distal end and having an interior space adequate to accommodate:

- a control structure;
- at least one operative guide channel;
- a fiberoptic line;
- an illumination fiberoptic line;

a guide face affixed to said distal end through which said operative guide channel opens and onto which said fiberoptic and illumination lines terminate; and,

a corner radius formed around the periphery of said guide face thereby tapering said distal end, thereby facilitating insertion of the distal end into a smaller opening than can be accomplished with a blunt distal end;

at least one operative port support on said control section connected to at least one operative guide channel;

an eye piece supported on said control section and connected to said fiber optic line;

an illumination port supported on said control section connected to said illumination fiber optic line;

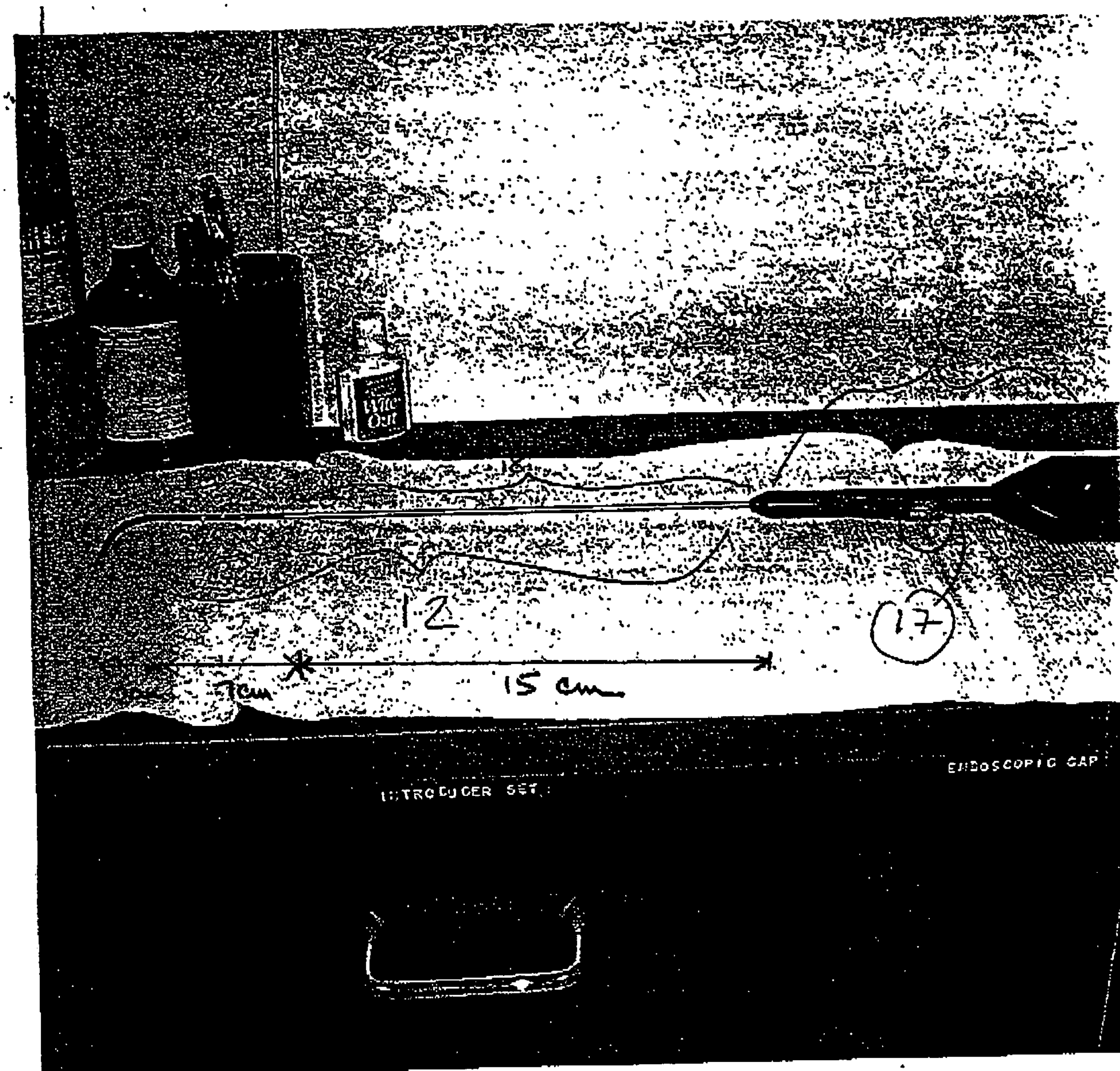
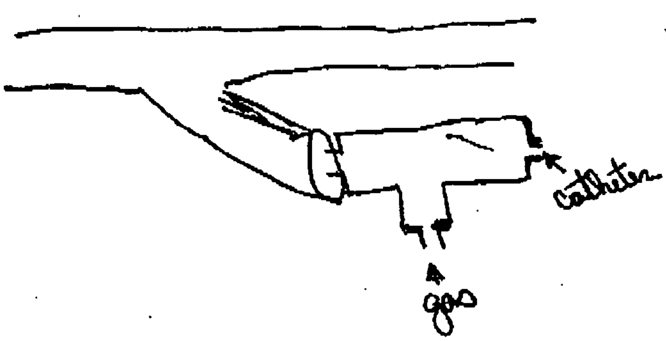


FIG 1A



to be replaced with a 3 way connector, -

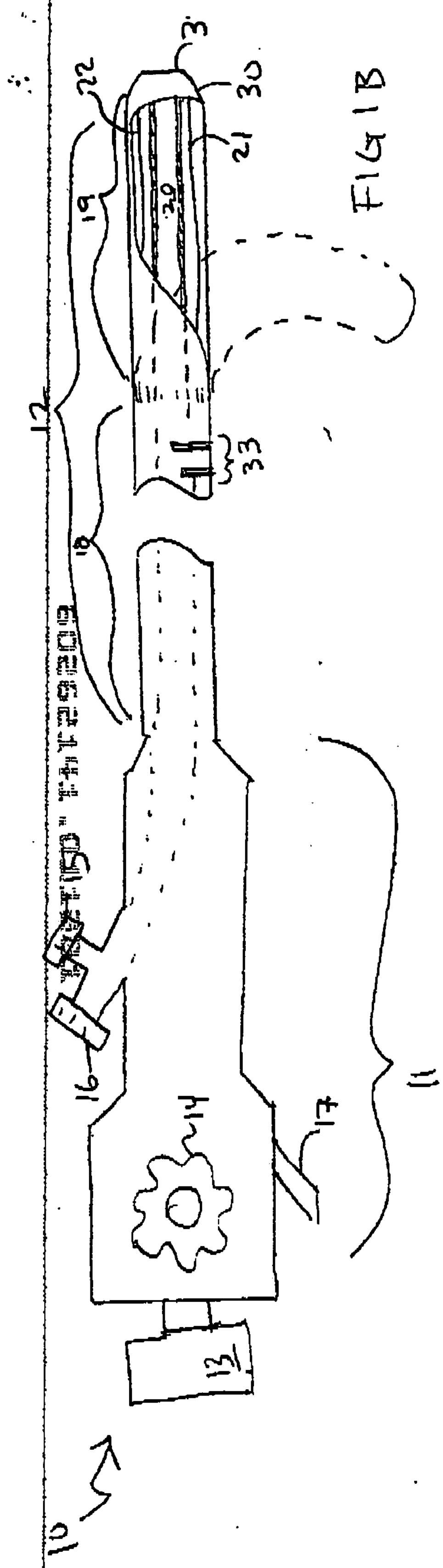


FIG 1B

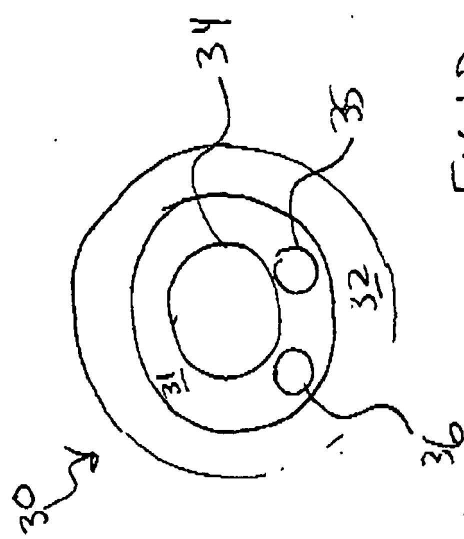


FIG 1D

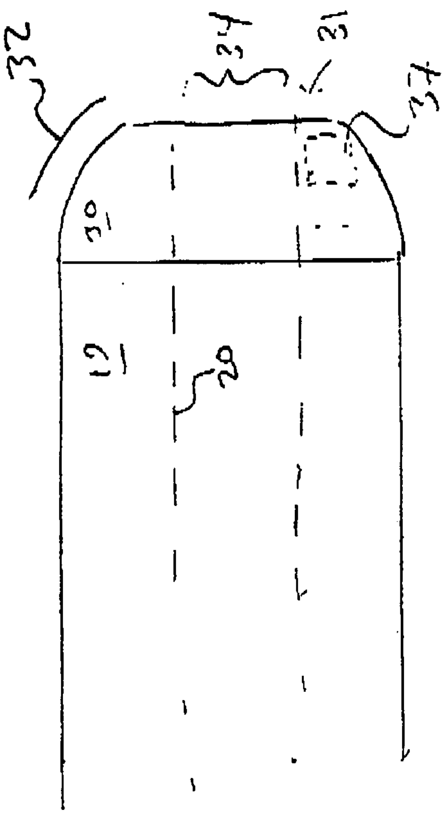


FIG 1C

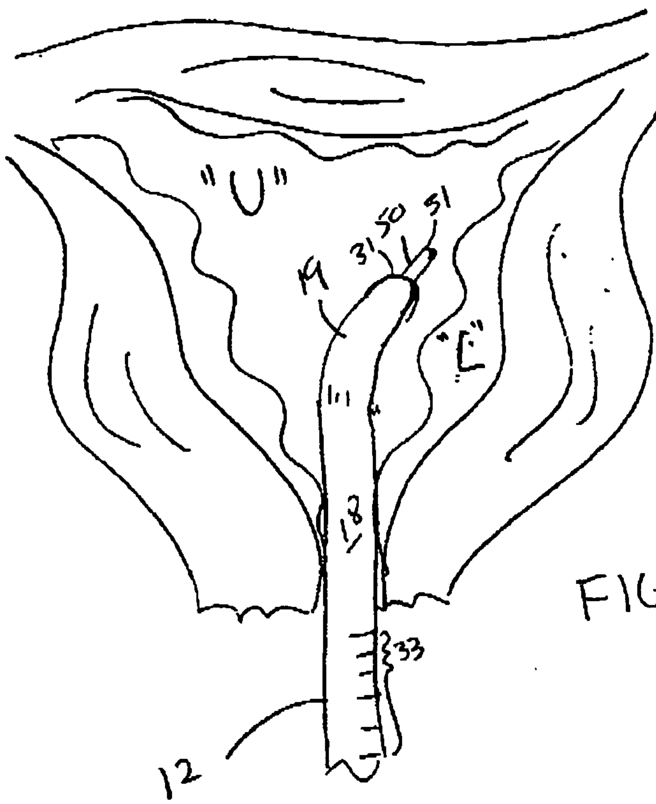


FIG 2A

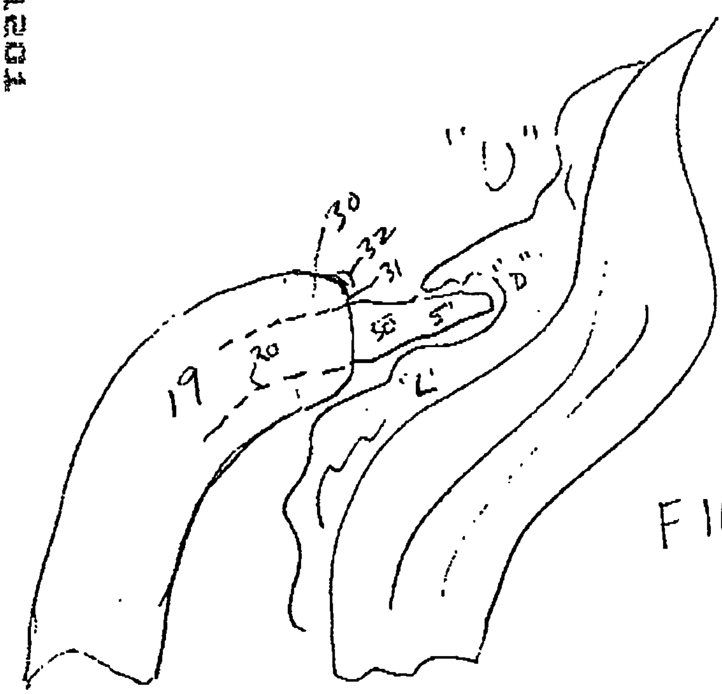
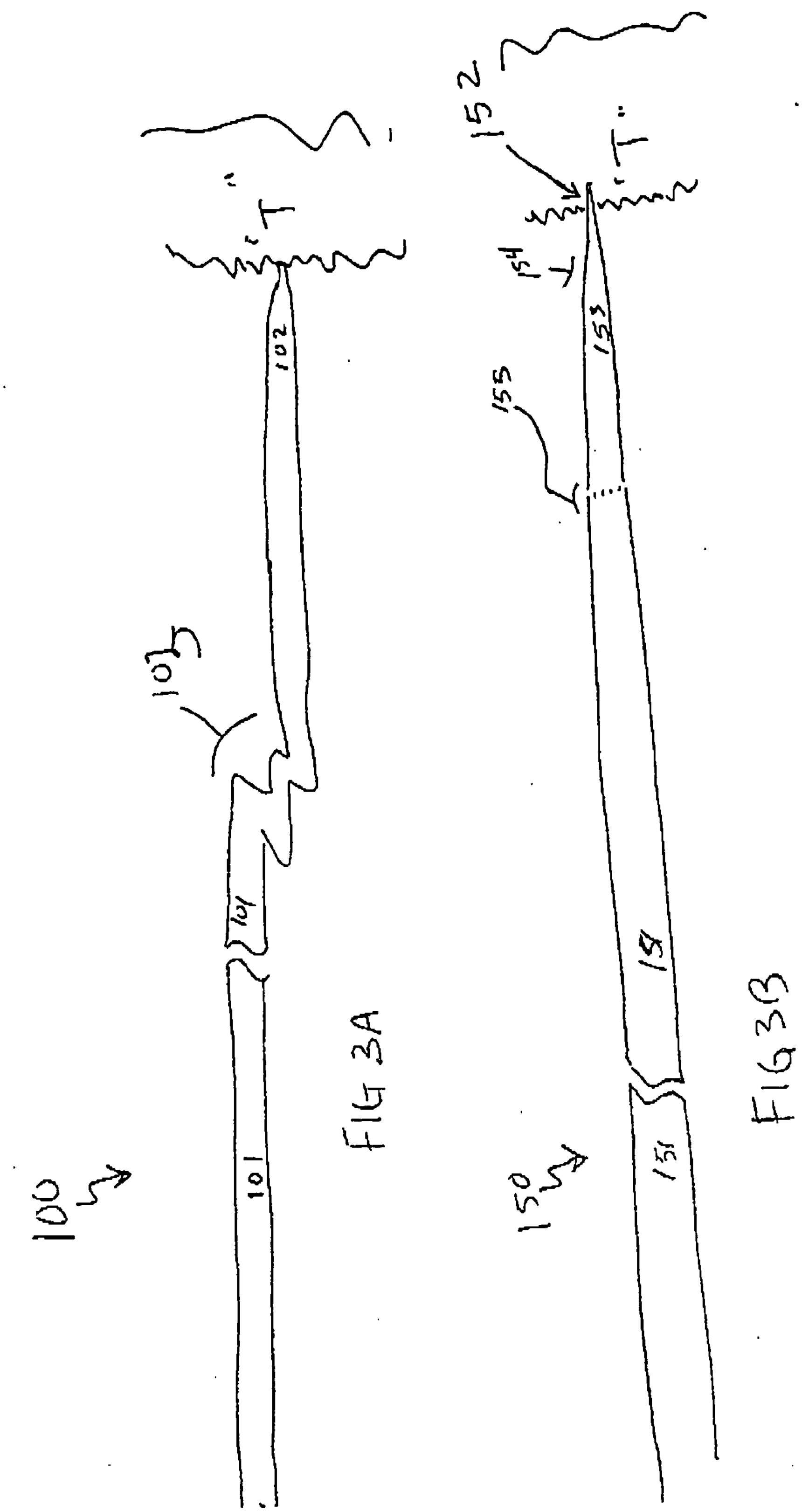


FIG 2B


100
101
101
102
103
"T"
FIG 3A
150
151
151
152
153
154
155
"T"
FIG 3B